K090582

SECTION 7

JUL - 2 2009

510 (k) SUMMARY

The following information summarizes the safety and effectiveness information upon which the substantial equivalence determination for the Calcaneal Fracture Plate System is based.

Prepared:	Monday, February 23, 2009
Applicant:	Tornier, Inc. 3601 West 76th Street Suite 200 Edina, MN 55435 **Registration Number:** 9100540
Telephone:	978-232-9997
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Contact:	Brahim Hadri (Sr. Regulatory Affairs Specialist (RAC US)
Device Name:	Calcaneal Fracture Plate System
Device Trade Name:	(tbd)
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3030, Single/multiple component metallic bone fixation appliances and accessories
Product Code:	LXT
Description:	The Tornier Calcaneal Fracture Plate System is a low profile, anatomical plate designed for the fixation of Calcaneal fractures. The plate has 7 screw holes, which accept 4mm diameter screws. The plates are 2.0 to 3mm thick, comes in 3 sizes (Large, Medium and Small) for optimal anatomic fit and are available for right and left placements. The Tornier Calcaneal Fracture Plate System is made out of 316L Stainless Steel material per ASTM F138.
Predicate Devices:	The Synthes Locking Calcaneal Plates, K991407. The Newdeal Calcanea™ Plate, K041786

SECTION 7

510 (k) SUMMARY (continued)

Indications for Use

The Tornier Calcaneal Fracture Plate System is indicated for fractures and osteotomies of the calcaneus, including, but not limited to extra-articular, intra-articular, joint depression, tongue-type and severely comminuted fractures.

Comparison of Technological Characteristics:
The Tornier Calcaneal Fracture Plate System, Synthes Locking Calcaneal Plates, and the Newdeal Calcanea™ Plate, K041786 have equivalent Intended Use and are indicated for fixation of fractures and osteotomies of the calcaneus
Like the predicate; the Tornier Calcaneal Fracture Plate System is offered in 316L Stainless Steel material per ASTM F138..

Conclusion:
The Tornier Calcaneal Fracture Plate System is substantially equivalent to commercially marketed devices, the Synthes Locking Calcaneal Plates, K991407 and the Newdeal Calcanea™ Plate, K041786
The Tornier Calcaneal Fracture Plate System does not raise any new issues of scientific technology, safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tornier, Inc.
% Mr. Brahim Hadri
Senior Regulatory Affairs Specialist
3601 West 76th Street, Suite 200
Edina, Minnesota 55435

JUL - 2 2009

Re: K090582
Trade/Device Name: Calcaneal Fracture Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: June 19, 2009
Received: June 30, 2009

Dear Mr. Hadri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 6
Indications for Use Statement

Indications for Use

510(k) Number (if known): N/A

Device Name: Calcaneal Fracture Plate System

Indications for Use:

The Tornier Calcaneal Fracture Plate System is indicated for fractures and osteotomies of the calcaneus, including, but not limited to extra-articular, intra-articular, joint depression, tongue-type and severely comminuted fractures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090582